IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC., Defendants.	C.A. No. 13-1524-SLR

PAR'S BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

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Takeda seeks to assert twelve new patents covering treatment of only *gout.* Yet, Par's product, limited to treatment of *Familial Mediterranean Fever* (FMF), does not mention gout, will not be approved for treating gout, and cannot be marketed to treat gout. Takeda's tardy request simply seeks to delay this case by adding a dozen irrelevant patents. Takeda's motion should be denied.

I. NATURE AND STAGE OF THE PROCEEDINGS

Takeda's COLCRYS (colchicine), the drug product at issue in this Hatch-Waxman action, has two approved indications: (1) treatment of gout; and (2) treatment of Familial Mediterranean Fever (FMF). Takeda listed seventeen method patents in the Orange Book as covering COLCRYS – twelve are directed to treating only gout, three are directed to treating only FMF, and two are directed to treating both diseases.

Par submitted an ANDA to the FDA for approval to market a generic colchicine product. At first, Par sought FDA approval to treat only gout, not FMF, and Takeda responded by suing Par for infringing its gout-related patents in April 2012.[1] In July 2013, after providing notice to Takeda, Par changed the sole indication sought in its ANDA from gout to FMF. With this change of indication, Par amended its patent certifications in its ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) (also known as "section viii" or "the carve-out provision"), certifying to the FDA that Takeda's patents relating to only gout are no longer relevant to Par's ANDA. After a hearing with this Court on July 23, 2013, where Takeda argued that Par's ANDA amendment warranted separate action on a separate track, this Court stayed the case relating to gout.[2]

[1] *See* C.A. No. 12-cv-419-SLR.
[2] *See* C.A. No. 12-cv-419-SLR, D.I. 98.

On August 30, 2013, Takeda commenced the current case against Par, alleging infringement of the five patents directed to FMF.[3] Nearly ten months later, Takeda now seeks to amend its complaint to add back in the twelve gout-specific patents ("gout patents") under a theory of contributory infringement, despite its inability to do so in light of the section viii carve-out provision. To date, the parties have served numerous document requests, produced thousands of documents, and are approaching the close of fact discovery, with fact depositions requested to begin in just weeks. Indeed, fact discovery closes in approximately two months.

Takeda first filed its motion for leave to amend its complaint on May 13, 2014. *See* D.I. 46. On the morning of May 30, the day Par was to file its opposition, Takeda withdrew and re-filed its motion, removing some of the legally futile allegations from its proposed amended complaint, which allegations Takeda asserted despite first-hand knowledge of their futility. *See* D.I. 52, 53. By withdrawing, changing, and re-filing its motion at the last minute, Takeda has forced Par to expend even more resources to re-draft its opposition, and delayed the disposition of its motion by resetting the briefing schedule.

II. SUMMARY OF THE ARGUMENT

1. This Court lacks subject matter jurisdiction to consider the contributory infringement claims Takeda now seeks to add. Takeda's claims are based upon speculations; there is no actual controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

2. Under Fed. R. Civ. P. 15(a)(2), this Court has discretion to deny leave to amend when there exists undue delay, bad faith, dilatory motive or undue prejudice to the opposing party, or when the amendment would be futile. *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir.

[3] Takeda alleged infringement of the three patents relating to treating only FMF, plus the two patents relating to treating both FMF and gout.

1993). Here, the Court must deny Takeda's motion; while Par needs to demonstrate the existence of only one, multiple reasons for denial exist here.

3. Takeda's contributory infringement claims are futile and will eviscerate section viii, which prohibits Takeda from using its gout patents to (1) force Par to engage in unnecessary patent infringement litigation; and (2) potentially delay FDA approval of Par's ANDA. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1681-82 (2012).

4. Takeda's contributory infringement claims are futile and fail as matter of law because Par's product is not especially made or adapted to infringe Takeda's gout patents, and constitutes a staple article capable of noninfringing commercial uses. *See* 35 U.S.C. § 271(c).

5. Takeda filed its motion with dilatory intent. Over the past few months, Takeda repeatedly tried to delay this case and, within one week of filing its now-withdrawn motion, Takeda attempted to delay scheduled depositions in this case until the Court *grants* its motion.

6. Takeda filed its motion after undue delay because it could have filed it by October 2013. Furthermore, by seeking to triple the number of asserted patents in this case, Takeda's amended complaint adds unwarranted burden for this Court, and causes Par undue prejudice.

7. Therefore, in light of all these reasons, this Court must deny Takeda's motion.

III. ARGUMENT

Takeda's motion to amend its complaint to add a dozen irrelevant patents should be denied. As an initial matter, this Court lacks subject matter jurisdiction to consider the declaratory judgment claims Takeda now tries to add. Short of demonstrating the existence of a controversy "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment," *MedImmune, Inc.*, 549 U.S. at 127, Takeda's proposed claims are contingent upon three speculative events: (1) if the FDA approves Par's ANDA; (2) if Par markets its product;

and (3) if Par's product will be used to treat gout even though it is approved to treat only FMF. With no guarantee that any of these events will occur, declaratory judgment is not appropriate, and this Court cannot exercise its subject matter jurisdiction here.

Even if this Court does exercise jurisdiction, it should deny Takeda's motion. Fed. R. Civ. P. 15(a)(2) allows a party to amend its pleading "only with leave of court or the written consent of the opposing party." *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000). While "leave shall be freely given when justice so requires," the Court has discretion to "deny leave to amend when there exists undue delay, bad faith, dilatory motive or undue prejudice to the opposing party, or when the amendment would be futile." *Smiley v. Daimler Chrysler*, 538 F. Supp. 2d 711, 715 (D. Del. 2008) (*citing Foman v. Davis*, 371 U.S. 178, 182 (1962)).

Here, numerous independent reasons exist for denying Takeda's motion. Takeda moves to amend with dilatory motives, and after undue delay. If allowed to more than triple the number of asserted patents, Takeda's proposed amendment will cause undue prejudice to Par. Most importantly, Takeda's amendment is futile – it is legally deficient and fails as matter of law, and it seeks to delay FDA approval of Par's ANDA with irrelevant patents, a move specifically prohibited by section viii and the Hatch-Waxman framework. The presence of *any* one of these reasons warrants denial of Takeda's motion.

A. This Court lacks subject matter jurisdiction to consider Takeda's contributory infringement claims.

As an initial matter, this Court should deny Takeda's motion to amend its complaint because it lacks subject matter jurisdiction to consider the claims Takeda now tries to add. Seeking declaratory judgment that Par's product will contribute to the infringement of Takeda's gout-related patents, Takeda has to prove that the facts alleged, "under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of

sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune,* 549 U.S. at 127. Takeda cannot.

Indeed, Takeda's contributory infringement claims are highly speculative, and are contingent on not one, not two, but *three* distinct hypothetical future events. First, because Par cannot market its product without FDA approval, Takeda's alleged contributory infringement is contingent on FDA approval of Par's ANDA. Takeda does not, and indeed cannot, allege that FDA approval is imminent or likely – the FDA has not approved Par's ANDA, and it is unclear if, and when, the FDA may do so. In fact, the earliest Par may receive FDA approval of its ANDA is January 2016, when the 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) expires. *See* D.I. 3. With such uncertainty, Takeda's claims lack sufficient immediacy and reality to warrant declaratory judgment. *Cf. Abbott Diabetes Care, Inc. v. DexCom, Inc.*, C.A.05-590 GMS, 2006 WL 2375035, at *3 n.3 (D. Del. Aug. 16, 2006) ("the absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate.").

Second, Takeda's contributory infringement claims are contingent on Par's decision to actually market its product. Again, it is uncertain when Par may make this decision (if at all), especially when Par cannot market its product until July 29, 2016, after the orphan drug exclusivity associated with COLCRYS expires. Meanwhile, potential changes in market conditions, potential manufacturing issues, and potential settlements may very well delay or even prevent Par's marketing of its product. *See Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938 (N.D. Ill. 1995) ("fact that Defendant requested FDA approval of its generic [drug] does not mean that Defendant will not change its course of actions and decide not to market the drug.").

Finally, because it is "axiomatic that there can be no inducement or contributory infringement without an underlying act of direct infringement," *In re Bill of Lading Transmission*

& Processing Sys. Patent Litig., 681 F.3d 1323, 1333 (Fed. Cir. 2012), Takeda's contributory infringement claims are contingent on an act of direct infringement: requiring that Par's product be given to a patient for gout, even though it can be FDA-approved to treat only FMF. Further, Takeda's proposed amended complaint does not allege who would directly infringe its gout-related patents, nor does it allege when such infringement would occur. Such hypothetical infringement is speculative, and lacks any immediacy or reality. "A claim is not ripe for adjudication if it rests upon "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998). Here, Takeda's parade of hypotheticals is not enough to trigger this Court's subject matter jurisdiction over its contributory infringement claims.

B. Takeda's proposed amended complaint is futile.

Even if this Court does exercise subject matter jurisdiction, and even if every allegation in its proposed amended complaint is true, Takeda fails to state a claim upon which relief can be granted, and its contributory infringement claims fail as matter of law. "Futility of amendment occurs when the complaint, as amended, does not state a claim upon which relief can be granted. Additionally, if the proposed amendment is frivolous or advances a claim or defense that is legally insufficient on its face, the court may deny leave to amend." *Smiley*, 538 F. Supp. 2d at 715. "[A]n amendment will be considered 'futile' if it cannot withstand a motion to dismiss," and the "claim must be futile as a matter of law rather than merely unlikely as a matter of fact." *Site Microsurgical Sys., Inc. v. Cooper Companies, Inc.*, 797 F. Supp. 333, 336 (D. Del. 1992).

Here, Takeda's proposed amended complaint is futile, because: (1) Takeda seeks to assert patents directed to an indication for which Par does not seek FDA approval, contrary to the section viii carve-out provision, and its contributory infringement claims conflict with the

mandates of the Hatch-Waxman Act; and (2) Takeda's contributory infringement claims are legally deficient and fail as matter of law, because Takeda cannot establish key prerequisites for holding Par liable – specifically, Takeda cannot establish that Par's generic colchicine product has no use other than to infringe Takeda's gout patents.

1. Takeda's proposed amendment is contrary to 21 U.S.C. § 355(j)(2)(A)(viii), a key provision of the Hatch-Waxman Act.

If allowed, Takeda's amended complaint effectively eviscerates the section viii carve-out provision, a critical aspect of the Hatch-Waxman Act that sets forth the process for FDA approval of generic drug applications for uses not claimed by a particular Orange Book-listed patent. Before the FDA can approve an ANDA, the ANDA applicant needs to resolve all patent issues between it and the brand drug company, often through Paragraph IV litigations.[4] But if a relevant method patent does not protect all approved uses of the brand drug product, the ANDA applicant may, pursuant to section viii, seek FDA approval for the uses not covered by that patent, and "carve out" the claimed use(s) from its label. *See* 21 U.S.C. § 355(j)(2)(A)(viii). By carving out the other claimed uses, the ANDA applicant ensures its product does not fall within the scope of the patents, and avoids the need to engage in Paragraph IV litigations over them.

Generic drug companies like Par routinely utilize section viii. Here, Par relied on section viii to seek FDA approval for only FMF.[5] Treatment of FMF is a non-claimed, and unpatented, use with respect to Takeda's gout patents. Because Takeda's twelve gout patents do not protect

[4] Where an ANDA applicant must first certify that the relevant patent protecting the brand drug is invalid, unenforceable, or will not be infringed by its proposed generic product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This certification allows the brand company to sue the ANDA applicant for patent infringement, commencement of which automatically stays the FDA approval of the ANDA for 30 months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

[5] COLCRYS, on the other hand, is indicated for treating both FMF and gout.

or claim the use of colchicine to treat FMF, and because Par seeks FDA approval for treating only FMF, Takeda's gout patents are irrelevant to Par's ANDA approval and indeed, this case.

If Takeda's proposed amended complaint is allowed, Takeda could, long before Par markets it generic colchicine: (1) force Par to engage in costly and prolonged patent infringement litigation involving irrelevant patents; and (2) if it is somehow successful on the merits, use these twelve irrelevant gout patents to delay FDA approval of Par's ANDA, and all generic competition, until all the patents expire. This is the opposite outcome the Hatch-Waxman Act, and specifically section viii, contemplated, where the Hatch-Waxman Act is "designed to speed the introduction of low-cost generic drugs to market," *Caraco Pharm. Labs., Ltd.*, 132 S. Ct. at 1676, and with section viii, expressly "permits an ANDA to be approved for less than all of the indications for which the listed drug has been approved." H.R. REP. 98-857, pt.1, at 21 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2654.

a) Takeda cannot force Par to engage in costly and unnecessary patent infringement litigation.

Takeda's amended complaint overlooks section viii's intention that the ANDA applicant avoid engaging in costly litigation over patents that do not protect its intended use. According to Rep. Henry A. Waxman, section viii "is a key feature of the Hatch-Waxman generic approval framework, designed to enable ANDA applicants… *to circumvent costly, prolonged Paragraph IV litigation* that would delay generic competition for years." Br. of Rep. Henry A. Waxman as *Amicus Curiae* in Support of Petitioners, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844, 2011 WL 3947565, at *12 (U.S. Sept. 6,2011) (the "Waxman Amicus Br.") (emphasis added). Whereas a Paragraph IV certification provokes litigation and a 30-month stay of FDA approval, "[t]he Hatch–Waxman Amendments authorize the FDA to approve the marketing of a generic drug for particular unpatented uses; and section viii provides the mechanism for a

generic company to identify those uses, so that a product with a label matching them can quickly come to market." *Caraco*, 132 S. Ct. at 1681.

Here, Par submitted section viii statements to "carve out" the twelve gout patents listed in the Orange Book for COLCRYS, and submitted Paragraph IV statements for the five patents that relate to treating FMF. If, however, Takeda's proposed amended complaint is allowed, Takeda would be able to assert *seventeen* patents against Par, even though twelve of them relate to an indication for which Par does not seek approval. Consequently, Par would be forced into the Paragraph IV litigation process to challenge these twelve patents, "the very process that the section viii alternative was designed to avoid, and that Congress recognized would delay generic competition for years." Waxman Amicus Br., 2011 WL 3947565, at *24 ; *cf. Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) (filing a Paragraph IV certification introduces "the hazard of sparking costly litigation"). In effect, despite its section viii statements, Par would find itself in the same situation as if it had submitted Paragraph IV certifications for all seventeen patents – which is contrary to the purpose of section viii.

b) Takeda cannot rely on irrelevant patents to delay approval of Par's ANDA.

If Takeda is allowed to assert its contributory infringement claims now and is ultimately successful on the merits of its claims, it will prevent or delay the approval of Par's ANDA with patents that cover an indication for which Par does not seek FDA approval. But this is the wrong result. The Hatch-Waxman Act expressly "permits an ANDA to be *approved* for less than all of the indications for which the listed drug has been approved." H.R. REP. 98-857, pt. 1 at 21 (emphasis added); *see also Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996). Indeed, "[a] section viii statement indicates that a patent poses *no bar to approval* of an ANDA because the applicant seeks to market the drug for a use other than the one encompassed

by the patent." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) (emphasis added). The *Purepac* court's interpretation is also consistent with FDA practice. *See, e.g.*, Letter Decision, FDA Docket No. 2008-P-0069, at 5 (July 28, 2008).[6]

Here, the gout patents Takeda now seeks to assert do not relate to the treatment of FMF. Thus, with respect to the gout patents, treating FMF is an *unpatented* use. The gout patents are not permitted to delay or affect approval of Par's ANDA or marketing of Par's product. *See Caraco*, 132 S. Ct. at 1681-82 ("The [Hatch-Waxman] scheme . . . contemplates that one patented use will not foreclose *marketing* a generic drug for other unpatented ones.") (emphasis added). Even if this Court ultimately concludes that Par does not infringe the gout patents, the presence of these irrelevant patents in this case will, in addition to subjecting Par and this Court to needless and costly litigation, necessarily have delayed the final disposition of this case, and will have affected the FDA's approval of Par's ANDA. Such a delay is inconsistent with the Hatch-Waxman Act, legislative intent, court holdings, and FDA practices. Thus, Takeda's request that this Court hold Par liable for infringing its gout patents, and enjoin Par from marketing its product during the life of these patents, D.I. 53-1 at 33, ¶¶ C, D, is contrary to law.

c) Takeda's purported "quandary" does not allow it to bypass the Hatch-Waxman framework.

During the June 2, 2014 Hearing with this Court in Case No. 14-268, Takeda complained to be in a "quandary" because physicians may prescribe generic colchicine product to treat gout, even if the generic product is not indicated to treat gout. *See* June 2 Hr'g. Tr. 7:17-8:12.[7] Courts, however, have already considered, and rejected, similar arguments. *See, e.g.*,

[6] *See* Ex. A (unless otherwise noted, all exhibits cited to in this opposition refer to exhibits attached to the Declaration of Stephen Yang, which declaration is filed with this opposition brief).
[7] Ex. B (the "June 2 Hr'g. Tr.").

AstraZeneca Pharm. LP v. Apotex Corp., 669 F.3d 1370, 1380 (Fed. Cir. 2012) ("AstraZeneca also argues that Section viii statements and restricted generic labeling ignore market realities because even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available. We find this argument unpersuasive."). The Fourth Circuit similarly concluded that the Hatch-Waxman Act allowed an ANDA applicant to carve out a protected use (such as treating gout here), even if its generic drug, once approved, could be used off-label for the carved-out indication. In *Sigma-Tau Pharm., Inc. v. Schwetz*, 288 F.3d 141, 146 (4th Cir. 2002), the Court declined the brand company's invitation to look beyond the ANDA applicant's label, and consider "compelling, readily available, objective evidence of the generics' intended use, such as market data . . . , dosage forms, and federal drug reimbursement policies" in determining whether the FDA could properly approve an ANDA. *Id.* at 145. The Court concluded that, in addition to being contrary to the Hatch-Waxman framework, such requirements would "frustrate the longstanding practice of Congress, the FDA, and the courts not to interfere with physicians' judgments and their prescription of drugs for off-label uses," and help establish "a regulatory regime in which relatively few generics are approved," where "the consequences of adding a huge evidentiary hurdle to the generic drug approval process would be profoundly anti-competitive." *Id.* at 147. Takeda's "quandary" does not allow it to ignore section viii and the Hatch-Waxman framework.

2. Takeda's contributory infringement claims are futile because they are legally deficient.

Takeda's proposed amended complaint is also futile because it cannot legally assert contributory infringement claims with its gout patents. 35 U.S.C. § 271(c) provides:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

To be liable for contributory infringement, an accused infringer must "sell, offer to sell or import into the United States a component of an infringing product knowing the component to be *especially made* or *especially adapted* for use in an infringement of such patent, and *not a staple article or commodity of commerce* suitable for substantial non-infringing use." *EON Corp. IP Holdings LLC v. FLO TV Inc.*, 802 F. Supp. 2d 527, 533 (D. Del. 2011) (emphases added).

Here, Takeda's proposed amendment is futile; *even if its allegations are true*, Takeda's contributory infringement claims fail as matter of law. Par cannot be liable for contributory infringement for at least two reasons under the law. First, Par's colchicine product is not especially made or especially adapted (as defined by case law) to treat gout; instead, it is specifically made and designed to treat FMF. Par's product thus cannot contributorily infringe Takeda's gout patents. Second, Par's colchicine product, while theoretically capable of treating gout if so prescribed by a doctor, has other commercial uses – treating FMF. Therefore, under controlling case law, Par's product constitutes a "staple article" as defined in the statute, precluding liability. Unable to establish all requisite elements, Takeda's contributory infringement claims fail as matter of law.

a) Par's colchicine product is not especially made or especially adapted to infringe Takeda's gout patents.

Takeda's contributory infringement claims are legally defective because the proposed label for Par's product firmly establishes that it is not "especially made or especially adapted for

use in an infringement" of Takeda's twelve gout patents. 35 U.S.C. § 271(c). To the contrary, Par's product is especially made to treat FMF and *only* FMF, and Par has certified to the FDA, via its section viii statements, that its product will *not* be used to treat gout, and asked the FDA to not approve its product to treat gout. Par cannot contributorily infringe Takeda's gout patents unless its product is *especially* made or adapted to treat gout; here, Par's product is not designed or intended to treat gout. Par simply cannot contributorily infringe Takeda's dozen gout patents.

In its proposed amended complaint, Takeda acknowledges that Par's current proposed product label is limited to the treatment of FMF, and is not directed to the treatment of gout. *See, e.g.*, D.I. 53-1 at 13, ¶ 34. In a proper infringement analysis, "the ANDA must be judged on its face for what an accused infringer seeks the FDA's approval to do." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). Par's label categorically establishes that its product would be especially made and adapted for treating *FMF*, not gout. Because Par's product is not especially made or adapted to treat gout, Takeda's contributory infringement claims fail as matter of law.

b) Par cannot be liable for contributory infringement because its generic product constitutes a staple article of commerce.

35 U.S.C. § 271(c) expressly provides that there can be no liability of contributory infringement if the component sold or offered for sale is a staple article of commerce suitable for substantial noninfringing use. Here, Par's generic colchicine product, once approved and marketed, would constitute such a staple article.

Takeda's proposed amended complaint acknowledges that upon approval, Par will sell its generic colchicine product for the treatment of FMF. *See* D.I. 53-1 at 15, ¶ 43. This alone absolves Par of any potential liability here because to be liable for contributory infringement, the accused product must be "unsuited for *any* commercial noninfringing use." *Sony Corp. of Am. v.*

Universal City Studios, Inc., 464 U.S. 417, 441 (1984) (emphasis added). Indeed, "[u]nless a commodity has no use except through practice of the patented method, the patentee has no right to claim that its distribution constitutes contributory infringement." *Id.*

As the Supreme Court explained, the "prohibition against contributory infringement is confined to the knowing sale of a component *especially made for* use in connection with a particular patent. There is no suggestion in the [Patent Code] that one patentee may object to the sale of a product that might be used in connection with other patents." *Sony Corp.*, 464 U.S. at 440 (emphasis added). The Supreme Court also concluded that Congress, seeking to balance the competing doctrines of patent misuse and contributory infringement, "granted to patent holders a statutory right to control *nonstaple* goods that are capable *only of* infringing use in a patented invention, and that are essential to that invention's advance over prior art." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 213 (1980). Indeed, this distinction between staple and nonstaple articles "ensures that the patentee's right to prevent others from contributorily infringing his patent affects only the market for the invention itself." *Id.* at 220.

Here, there is no dispute that upon approval, Par's generic colchicine product will be labeled for treating FMF, a commercial use that cannot infringe Takeda's gout patents. Consequently, Par's generic colchicine product is not "unsuited for any commercial noninfringing use," *Sony Corp.*, 464 U.S. at 441, and is not a nonstaple article capable *only* of infringing Takeda's gout patents.[8] Takeda cannot rely on its twelve gout patents to affect Par's commercial activities outside the market those patents protect. Again, Takeda's contributory infringement claims fail as matter of law.

c) Takeda mischaracterizes the case law for support.

[8] Takeda's allegations that Par's product is capable of infringing its gout patents, if so prescribed by a doctor, are also speculative at best.

Finally, the case law Takeda relies on does not support its conclusions. Takeda concludes that "[c]ontributory infringement claims under 35 U.S.C. § 271(c) are permissible when the proposed generic label 'carves out' the patented indication." D.I. 54 at 14. Not so.

Takeda's faulty conclusion is premised on its misplaced reliance on *Novartis Pharm., Corp. v. Wockhardt USA LLC*, No. 12-CV-3967, 2013 WL 5770539 (D.N.J. Oct. 23, 2013). *Novartis* simply does not stand for the proposition Takeda wishes it did. There, the Court denied Defendants' motion to dismiss Plaintiff's contributory infringement claim, not because it affirmatively concluded that such a claim is "permissible," but only because it did not yet want to decide whether the claim was facially insufficient at the pleadings stage to warrant dismissal – the Court did not address the merits of the claim, nor did it address the parties' arguments. *See id.* at *10. While the Court in *Novartis* mentioned that "whether the disputed non-infringing use-treatment of Paget's disease is 'substantial' cannot be done at the pleadings stage," *id.*, there is no support for Takeda's conclusion that the Court "rejected defendants' arguments that 'an FDA approved indication is necessarily substantial.'" D.I. 54 at 16.

Conversely, in *Aventis Pharma Deutschland GmbH v. Cobalt Pharm., Inc.*, 355 F. Supp. 2d 586 (D. Mass. 2005), the Court faced a very similar set of facts and, after actually analyzing the issue, unequivocally held that the brand drug company may not pursue a contributory infringement claim. There, the brand drug, ALTACE, was approved for three distinct uses: (1) treating hypertension; (2) treating heart failure; and (3) reducing the risk of heart attack, stroke, and death from cardiovascular causes. *Id.* at 588. After Aventis (the brand company) listed in the Orange Book a method patent that covered only treating heart failure, Cobalt (the ANDA applicant) filed a section viii statement with the FDA and "carved out" treating heart failure from its proposed label. Nevertheless, Aventis amended its complaint to allege that Cobalt would

indirectly infringe this method patent under 35 U.S.C. §§ 271(b) and 271(c). *Id.* at 590. The court summarily rejected Aventis's induced infringement claim under § 271(b), *id.* at 598-99, and needed just one footnote to dispose of Aventis's legally deficient contributory infringement claim under § 271(c). *See id.* at 599 n.134 (holding the other uses for which the ANDA applicant seeks FDA approval are substantial non-infringing uses).

Finally, in both its proposed amended complaint and its accompanying brief, Takeda goes to great lengths to argue that the FMF market in the United States is insignificant. This is a red herring. Takeda proffers no support for its assertion that an FDA-approved treatment of a less common disease cannot constitute a substantial non-infringing use, nor is Par aware of any such support.[9] Indeed, *Aventis* squarely rejects Takeda's assertion. *Id.* at 599 n. 134.

C. Takeda filed its motion with dilatory motives.

This Court should also deny Takeda's motion for leave to amend its complaint, because Takeda's motion is dilatory in nature. *See Smiley*, 538 F. Supp. 2d at 715 (the Court may deny leave to amend when there is dilatory motive); *City of Perth Amboy v. Safeco Ins. Co. of Am.*, 539 F. Supp. 2d 742, 748 (D.N.J. 2008) ("In considering the nature of the delay, a plaintiff's conduct may be found dilatory when the purpose of the delay was to unnecessarily prolong litigation."). Here, Takeda has demonstrated its intent to further delay this case, and to seek to have the trial date, currently scheduled for August 2015, pushed back yet again. *See* D.I. 18.

Takeda has repeatedly attempted to delay its case against Par. For example, Takeda attempted to delay fact discovery by refusing to timely respond to Par's letters, *see* Ex. C at 1, by

[9] Takeda also goes to great lengths in its proposed amended complaint and brief to allege that Par intends to sell its generic colchicine product for the treatment or prevention of gout. *See, e.g.*, D.I.53-1 at 9, ¶ 24. Takeda conflates the concept of contributory infringement with that of induced infringement. Takeda does not, and could not, allege that Par intends to induce infringement of its twelve gout patents.

repeatedly providing meet-and-confer availabilities falling outside of Par's windows of availabilities, *see id.*; Ex. D, by refusing to provide availabilities for third party depositions (whom Takeda's counsel represent), *see* Ex. E; Ex. H at 6, and by delaying the deadline for completion of document production. *See* D.I. 41.

Takeda first filed its motion here on May 13, 2014. *See* D.I. 46. On May 29, one day before Par's opposition is to be filed, Takeda informed Par that it "identified some errors in [its] identification of the statutory provisions under which [it] would assert new claims for contributory infringement," Ex. F, and proceeded to withdraw and re-file its motion on May 30. *See* D.I. 52, 53. Takeda's re-filed motion removed its infringement allegations under 35 U.S.C. § 271(e)(2).[10] In reality, Takeda removed, at the last minute, futile allegations it asserted despite knowing their futility. Indeed, Takeda admitted in open court that it could not assert its gout patents against Par under § 271(e)(2):

> MS. BOURKE: [*W*]*e would not be able to assert a claim under 271.E2 [sic, 271(e)(2)] if the indication had been carved out,* which the FMF indications have been carved out in February, *and there is, as I said, controlling Federal Circuit precedent that says we don't have a claim for relief under 271E.2 [sic, 271(e)(2)] under Section 8 [sic, viii].*

July 23, 2013 Hr'g. Tr. 20:1-9 (emphases added); *see also id.* at 20:21-22.[11,12]

Moreover, within just one week of having filed its now-withdrawn motion for leave to amend complaint, Takeda already tried to use its motion to delay this case. After first providing dates for third-party witness depositions in July, Takeda, whose counsel also represents these

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[10] *See* D.I. 46-1, ¶¶ 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, and 176 (alleging that Par's ANDA submission "constitutes infringement of one or more claims of the [gout patents] under 35 U.S.C. § 271(e)(2)(A)").

[11] Ex. G (the "July 23, 2013 Hr'g. Tr.").

[12] The "controlling Federal Circuit precedent" Takeda's counsel, Ms. Bourke, was referring to is *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012). *See* July 23 Hr'g. Tr. 19:7-9. Ms. Bourke argued before the Federal Circuit in that case.

third-party witnesses, made clear that it will not allow Par to depose the witnesses if its motion for leave to amend the complaint "is not granted within a week of the scheduled depositions." *See* Ex. H at 2; *see also* Ex. I. Even though Par served subpoenas upon these witnesses in March 2014, weeks after providing Takeda's counsel with courtesy copies of the subpoenas, Takeda's counsel did not provide these witnesses' availabilities until May 16, after repeatedly ignoring Par's numerous requests for availabilities. *See id.* at 4. By holding the scheduled depositions hostage until this Court *grants* its motion, Takeda is using its motion to further delay this case.

Takeda's dilatory conduct here is not surprising. *See* Waxman Amicus Br., 2011 WL 3947565, at *24 ("[I]t is a victory in and of itself for a brand company to lock a generic company into Paragraph IV litigation that will maintain the stay and delay the onset of generic competition, regardless of the eventual outcome of the litigation."). Takeda may not, however, use its pending motion as a tool to prolong this litigation. Takeda's motion must be denied.

D. Takeda's amendment is caused by undue delay, and will cause undue prejudice to Par.

Takeda first notified Par of its intent to amend the complaint in mid-May, almost nine months after it filed its complaint against Par last August. Since then, the parties have finished producing documents, and are in the midst of fact discovery. Par has served subpoenas and deposition notices, and has been preparing to take the noticed depositions. While Takeda managed to file its motion for leave to amend complaint before the deadline to amend pleadings, *see* D.I. 18, it had previous opportunities to amend its complaint. Takeda's amended complaint would place an unwarranted burden on the Court, and cause Par substantial and undue burden.

1. Takeda filed its motion with undue delay.

While "delay alone is an insufficient ground to deny leave to amend . . . at some point, the delay will become undue, placing an unwarranted burden on the court, or will become

prejudicial, placing an unfair burden on the opposing party." *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001). "Delay may become undue when a movant has had previous opportunities to amend a complaint." *Id.* Here, while it claims it has sought to amend its complaint "as timely as possible," D.I. 54 at 10, Takeda has in fact had ample opportunities to amend its complaint, and could have done so much earlier.[13]

Indeed, Takeda could have asserted its twelve gout patents against Par last August, when it filed its original complaint and asserted the five FMF patents against Par. As of August 2013, Takeda had the information it now relies on in justifying its motion to amend the complaint. Takeda's argument that it first needed to obtain more documents from Par, and needed discovery from Par to confirm Par's intent, *see* D.I. 54 at 8-9, is a red herring and does not excuse Takeda's undue delay. As Takeda itself recognizes, Par's actual intent is legally irrelevant for contributory infringement liability. *See* D.I. 54 at 13 (citing *Bone Care Int'l, L.L.C. v. Roxane Labs., Inc.*, 09-CV-285 GMS, 2012 WL 2126896 (D. Del. June 11, 2012), for the proposition that "intent is presumed in a contributory infringement analysis").

In addition, Takeda (wrongly) contends that *Novartis* held contributory infringement claims are permissible when the ANDA applicant's label carved out patented indications pursuant to section viii. *See* D.I. 54 at 14. But, *Novartis* became publicly available as of October 23, 2013. If Takeda needed that order to justify asserting all its gout patents, it could have sought to amend its complaint by late October of last year.

Takeda's proposed amended complaint also places unwarranted burden on this Court. Whereas Takeda has currently asserted five patents, Takeda now seeks to assert seventeen patents against Par. As this Court recognizes, "adding even one claim in some patents can be a

[13] Takeda's counsel refused to provide the reasons for its decision to amend the complaint now, as opposed to months ago, claiming the reasons as "irrelevant" and "privileged." *See* Ex. H at 5.

tremendous amount of work." July 23 Hr'g. Tr. at 12:19-21. Adding an indefinite number of claims from a *dozen* patents, however, makes this case extraordinarily difficult to adjudicate.

2. Takeda's amended complaint will cause Par undue prejudice.

Takeda's proposed amended complaint would also cause substantial and undue burden to Par. "[A] district court has the discretion to deny such a request if amendment would result in 'undue prejudice' to the opposing party." *Trueman v. City of Upper Chichester*, 289 F. App'x 529, 533 (3d Cir. 2008). "The issue of prejudice requires that we focus on the hardship to the defendants if the amendment were permitted. Specifically, we have considered whether allowing an amendment would result in additional discovery, cost, and preparation to defend against new facts or new theories." *Cureton*, 252 F.3d at 273.

Takeda's claim that the parties could "simply resume where discovery had left off at the time of Par's decision to amend its label," D.I. 47 at 11, ignores reality – Takeda now seeks to proceed under a wholly new infringement theory. More importantly, Par will need to defend itself against seventeen patents instead of five, which will force Par to expend tremendous amounts of additional cost and resources in developing its defenses and claims, and in engaging in additional discovery. In light of Takeda's undue delay, and the undue burden and prejudice the Court and Par face, this Court must deny Takeda's motion for leave to amend its complaint.

IV. CONCLUSION

This Court lacks subject matter jurisdiction to consider the contributory infringement claims Takeda now tries to assert. Even if this Court exercises jurisdiction, Takeda's motion for leave to amend its complaint is futile. Filed after undue delay, Takeda's motion is prejudicial and dilatory, and should be denied.

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